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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,029	08/27/2003	Jeffrey M. Ondrla	DEP5108	6457

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PHILIP S. JOHNSON  
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ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/650,029	ONDRLA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/27/2003</u>                                                 | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election without traverse of **Group/Invention I** (claims 1-40), **Fixture:** Species A (embodied in Figure 1), **Prosthesis:** Species B (embodied in Figure 10), and **Trial:** Species A (embodied in Figure 7) in the reply filed on January 24, 2007 is acknowledged.
2. Claims 26 and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group/Invention and Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 24, 2007.

### *Drawings*

3. This application has been filed with informal drawings. It is difficult to discern the relationship between fixture 2, pins members 14, 20, and 22, securing features 34, and medullary canal 8 of long bone 10. Formal drawings will be required when the application is allowed.

### *Claim Objections*

4. Claim 18 is objected to because of the following informality: it is identical to claim 15 (claims exact same limitation, and depends on the same claim). Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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a. Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

(i) In each of claims 1, 11, and 21, the Applicants positively recite part of a human, i.e., “*said member extending from said body through at least a portion of the long bone and into the medullary canal*”. Thus claims 1, 11, and 21 include a human or living tissue within their scope and are non-statutory (see M.P.E.P. 2105). The Examiner respectfully suggests replacing “*said member extending from said body through at least a portion of the long bone and into the medullary canal*” with --*said member extending from said body and adapted to extend through at least a portion of the long bone and into the medullary canal*--.

A claim directed to or including within its scope a human or living tissue is not considered to be patentable subject matter under 35. U.S.C. 101. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable. The grant of a limited, but exclusively property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 Fed.Cir.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 4, 10, 13, 14, 20, 25, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Regarding claim 3, the limitation “said body comprises a ring” is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (or clamp-shaped). Claims 4 and 10 depend on claim 3.
- b. Regarding claim 13, the limitation “said body comprises a ring” is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (or clamp-shaped). Claims 14 and 20 depend on claim 13.
- c. Regarding claim 25, the limitation “said body comprises a ring” is indefinite as to the scope of the invention. Body 12 as shown in Figures 1-3 (elected Fixture species) is not ring-shaped (or annular-shaped), but half-moon-shaped (or clamp-shaped). Claim 32 depends on claim 25.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-25 and 27-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Masini (US 6,267,785 B1; cited in Applicants' IDS).

Referring to Figures 3-7, Masini discloses a positioning fixture *for positioning* at least one of a trial and a prosthesis (see column 7, lines 4-23) in the medullary canal (cavity 312) of a long bone (bone 315), said fixture comprising a body (assembly comprising collar 330, assembly comprising ring 406, assembly comprising clamp 550) and first, second, and third members

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(**Figure 3:** thumb screws 332 attached to collar 330, gasket 334, and/or rod 342; **Figure 4:** thumb screws attached to ring 406 and/or rods 408/420 having collar 422, see column 6, lines 15-18; **Figure 5:** thumb screws 552/554 attached to clamp 550, rods 520/540, and/or bolt 506) *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal, said member *adapted to support* at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figure 3:** external periphery of stem, ring 350, and/or bore through longitudinal axis of trial/prosthesis; **Figure 4:** ring 350 and/or external periphery of stem; **Figure 5:** bore through longitudinal axis of trial/prosthesis and/or external periphery of stem; **Figure 6:** fin having cross-bores). As shown in Figures 3 and 5, the body is generally crescent-shaped. As shown in Figure 4, the body is ring-shaped. With regards to dependent claim 4, see Figure 5 wherein the first portion is the main body of clamp 550 and the second portion (movably attached to the first portion) is screw 546. The “securing feature” could be the inner/inside wall of the body, which frictionally engages (“for securing”) the fixture to the long bone. With regards to independent claims 33 and 37, the trial/prosthesis disclosed by Masini comprises the structural limitations as claimed, and any of said trial or prosthesis is capable of being used with a positioning fixture comprising a body and a member engaging a “cooperation feature” of said trial or prosthesis.

10. Claims 1-6, 9-15, 18-25, 27, and 31-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Manasas et al. (US 6,371,991).

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Referring to Figures 1-8, Manasas et al. disclose a positioning fixture (alignment guide 10) *for positioning* at least one of a trial and a prosthesis in the medullary canal (cavities 21, 22) of a long bone (bone 20), said fixture comprising a body (**Figures 1-3**: guide portion 12 and/or taper 19; **Figures 4-8**: alignment body 14 and/or outer shape 150) and first, second, and third members (**Figures 1-3**: protrusions 13 and/or grooves/notches 16; **Figures 4-8**: angled guide surface features 142) *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal (see Figures 1, 2, and 8), said member *adapted to support* at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figures 1 and 2**: longitudinal flutes 31, or longitudinal grooves formed between longitudinal flutes 31; **Figures 5-8**: longitudinal flutes 132, or longitudinal grooves formed between longitudinal flutes 132). As shown in Figures 3-5 and 7, the body is generally crescent-shaped or half-moon shaped. As shown in Figure 3, the body may comprise a ring shape (e.g., opening 14). With regards to claim 4, the “first portion” is one end of the body, and the “second portion” is the other end of the body, wherein one end is “movably attached” (broadly interpreted as “if one portion moves, the other portion moves as well”) to the other end. The “securing feature” could be the inner/inside wall (or an external portion or surface) of the body, which frictionally engages (“for securing”) the fixture to the long bone. With regards to independent claims 33 and 37, the trial/prosthesis disclosed by Manasas et al. comprise the structural limitations as claimed, and any of said trial or prosthesis is capable of being used with a positioning fixture comprising a body and a member engaging a “cooperation feature” of said trial or prosthesis.

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11. Claims 1-9, 11-19, 21-25, 28, 29, 31, and 33-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pellet (US 2,765,787).

Referring to Figures 1-9, Pellet disclose a positioning fixture *for positioning* at least one of a trial and a prosthesis in the medullary canal (canal 27) of a long bone (bone 28), said fixture comprising a body (**Figures 1-4:** acetabulum lock 22, flexible wire 36, and/or connector 44; **Figures 5-9:** acetabulum lock, symmetrical washer(s) 60, asymmetrical washer(s) 61, and/or flexible member 53) and a member (**Figures 1-4:** screw 46; **Figures 5-9:** screw 71) *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal (see Figures), said member *adapted to support* at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figures 1-4:** four longitudinal flanges 25, each comprising notches 47; **Figures 5-9:** nut 70 and/or washer 69). As shown in Figures 4 and 6-10, the body may comprise a ring shape. With regards to claim 4, the “first portion” is one end of the body, and the “second portion” is the other end of the body, wherein one end is “movably attached” (broadly interpreted as “if one portion moves, the other portion moves as well”) to the other end. The “securing feature” could be the inner/inside wall (or an external portion or surface) of the body, which frictionally engages (“for securing”) the fixture to the long bone. With regards to independent claim 33, the prosthesis disclosed by Pellet comprises the structural limitations as claimed, and said prosthesis is capable of being used with a positioning fixture comprising a body and a member engaging a “cooperation feature” of said prosthesis. With regards to the “second member” and the “third member”, no structural limitations has been



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claimed for any of those members, so any portion or link of the flexible member, and/or two washers will be considered to be the “second member” and the “third member”.

12. Claims 1, 2, 5-12, 15-24, and 28-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kenyon et al. (US 5,342,362 A).

Referring to Figures 1-4, 7, 10, and 11, Kenyon et al. disclose a positioning fixture (adaptor 30 and/or indicator 110) *for positioning* at least one of a trial and a prosthesis in the medullary canal of a long bone, said fixture comprising a body (**Figures 1-3 and 11: housing 32; Figures 7, 10 and 11: clamp 124**) and members (**Figures 1-3 and 11: nipples 48 and/or cylindrical portion 37; Figures 7, 10 and 11: anchor pin 96**) *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal, said member *adapted to support* at least one of the trial (see Figure 10) and the prosthesis (see Figure 11) as the one of the trial and the prosthesis is positioned with respect to the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figures 1-3 and 11: grooves on top of the trial/prosthesis receiving nipples 48 and/or groove on the side of the trial/prosthesis receiving cylindrical portion 37; Figures 7, 10 and 11: transversal grooves and/or longitudinal grooves on stem 6, 100**). As shown in Figure 10, the body (e.g., clamp 124) is generally crescent-shaped or half-moon shaped. With regards to claim 4, the “first portion” is one end of the body, and the “second portion” is the other end of the body, wherein one end is “movably attached” (broadly interpreted as “if one portion moves, the other portion moves as well”) to the other end. Also, housing 32 comprises leg 35 and arm 36 (see Figures 1-3). The “securing feature” could be the inner/inside wall (or an external portion or surface) of the body, which frictionally engages (“for securing”) the fixture to the long bone.

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Also, the "securing feature" could be nipples 48 and/or arms 44,46 (Figures 1-3) or connection port 116 (Figures 7, 10, and 11). With regards to independent claims 33 and 37, the trial/prosthesis disclosed by Kenjon et al. comprise the structural limitations as claimed, and any of said trial or prosthesis is capable of being used with a positioning fixture comprising a body and a member engaging a "cooperation feature" (e.g., longitudinal grooves alongside the generally circular cross section of the external periphery of said trial or prosthesis).


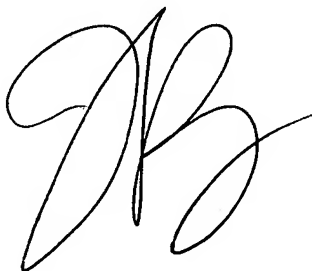
### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

April 12, 2007



David H. Willse  
Primary Examiner